JUL 25 2011

3. 510(k) Summary

1. 510(k) Owner	Gold Standard Orthopaedics, LLC 1226 Rowan Street Louisville, KY 40203 Contact Information: Phone: 502-581-8770 Fax: 502-581-1704 Establishment Registration Number: 3006215390 Owner/Operator Number: 10023859
2. Applicant / Sponsor	Gold Standard Orthopaedics, LLC 1226 Rowan Street Louisville, KY 40203 Contact Information: Phone: 502-581-8770 Fax: 502-581-1704 Establishment Registration Number: 3006215390 Owner/Operator Number: 10023859
3. Contact Person	James Ritter Aquila Consultants, LLC 3415 N. Old Farm Rd. E. Warsaw, IN 46582 Phone: (574) 527-3256 Fax: (574) 267-7516
4. Device Proprietary Name	GSO ACP1 Anterior Cervical Plate System
5. Device Common Name	Anterior cervical plate system
6. Date Summary Prepared	March 29, 2011
7. Classification Name	Spinal intervertebral body fixation orthosis, 21 CFR 888.3060

8. Legally Marketed Predicate Device	The GSO ACP1 Anterior Cervical Plate System was shown to be substantially equivalent in indications for use, design, mechanical testing, and materials to other commercially available anterior cervical plate systems cleared for distribution through the 510(k) process including: • Medtronic Sofamor Danek Atlantis Vision Anterior Cervical Plate, 510(k) Number K021461, cleared July 22, 2002 • Synthes Cervical Spine Locking Plate (CSLP), 510(k) Number K030866 cleared for distribution on April 18, 2003 • Blackstone Medical Anterior Cervical Plate, 510(k) Number K974885 cleared for distribution on June 17, 1998 • Life Spine, LLC, NEO™ Cervical Plating System, 510(k) Number K040844, cleared for distribution on July 23, 2004 • Spinal USA, Slimplicity Anterior Cervical Plate System, 510(k) Number K060025, cleared for distribution on April 18, 2006 • EBI, L.P., VueLock Anterior Cervical Plate System, 510(k) Number K023133, cleared for distribution on October 18, 2002
9. Device Description	The ACP1 Anterior Cervical Plate System consists of a variety of anterior cervical spinal bone plates and self-drilling / self-tapping bone screws for fixation of the vertebral body(s) of the cervical spine, using an anterior approach for the development of a cervical spinal fusion (C2-C7), and associated instruments. The bone screws form an interlocked construct on the vertebral bodies. The spinal bone plates include an integrated bone screw locking mechanism consisting of an integrated tab retained by a captive locking screw, covering a portion of the underlying bone screw head to prevent bone screw back-out. The bone screws are self-drilling / self-tapping, in various diameters and lengths, and are available in variable angle and fixed angle configurations. All implant components are ASTM standard, medical implant grade titanium alloy (Ti 6Al-4V ELI). The ACP1 system was designed to be compatible with common surgical instruments available in operating rooms equipped for spine surgery. The device specific instruments are considered to be Class II. The instruments are medical grade stainless steel, some have silicone rubber handles, and they are provided non-sterile. Stainless steel and titanium implant components must not be used together in a construct.
10. Intended Use	The GSO ACP1 Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion (C2-C7). The GSO ACP1 Anterior Cervical Plate System is intended for single use only.

11. Indications	The GSO ACP1 Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions. **WARNING:** This device system is intended for anterior cervical interbody fusions only. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
12. Summary of Technologies and Substantial Equivalence	The GSO ACP1 Anterior Cervical Plate System is substantially equivalent in indications for use, design, and materials to other commercially available anterior cervical plate systems cleared for distribution through the 510(k) process including: the Medtronic Sofamor Danek Atlantis Vision Anterior Cervical Plate, 510(k) Number K021461, cleared July 22, 2002, the Synthes Cervical Spine Locking Plate (CSLP), 510(k) Number K030866 cleared for distribution on April 18, 2003, and the Blackstone Medical Anterior Cervical Plate, 510(k) Number K974885 cleared for distribution on June 17, 1998, the Life Spine, LLC NEO™ Cervical Plating System, 510(k) Number K040844, cleared for distribution on July 23, 2004, the Spinal USA Simplicity Anterior Cervical Plate System, 510(k) Number K060025, cleared for distribution on April 18, 2006, and the EBI VueLock™ Anterior Cervical Plate System, 510(k) Number K02313, cleared for distribution on October 18, 2002.
13. Non-Clinical Testing	Mechanical testing to determine substantial equivalence to predicate devices was conducted according to ASTM F1717 including static compressive bending, static torsional stiffness, and dynamic axial compression bending.
14. Clinical Testing	Clinical testing was not necessary to demonstrate the substantial equivalence of the GSO ACP1 Anterior Cervical Plate System to the Medtronic Sofamor Danek Atlantis Anterior Cervical Plate, the Synthes Cervical Spine Locking Plate (CSLP), the Blackstone Medical Anterior Cervical Plate, the Life Spine, LLC NEO™ Cervical Plating System, the Spinal USA Simplicity Anterior Cervical Plate System, and the EBI VueLock™ Anterior Cervical Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gold Standard Orthopaedics, LLC
% Aquila Consultants, LLC
Mr. James Ritter
3415 North Old Farm Road East
Warsaw, Indiana 46582

JUL 25 2011

Re: K110990
Trade/Device Name: GSO ACP1 Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 08, 2011
Received: June 13, 2011

Dear Mr. Ritter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

Device Name: GSO ACP1 Anterior Cervical Plate System

Indications For Use:
The GSO ACP1 Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- spondylolisthesis
- trauma (including fractures)
- spinal stenosis
- tumors, deformity (defined as kyphosis, lordosis, or scoliosis)
- pseudarthroses, and/or failed previous fusions

WARNING: This device system is intended for anterior cervical interbody fusions only. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110990